# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 07-0794V**

**Filed: 30 March 2010**

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| JOSEFA REED, as legal guardian for her husband, DAVID F. REED, | * | |
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| Petitioner, | * | |
| | * | |
| v. | * | **UNPUBLISHED DECISION**[1] |
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| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| | * | |
| Respondent. | * | |
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*William Dobreff, Esq.,* Dobreff & Dobreff, Warren, Michigan, for Petitioner;
*Althea Walker Davis, Esq.*, United States Department of Justice, Washington, District of Columbia, for Respondent.

## RULING ON ENTITLEMENT BASED UPON THE WRITTEN RECORD AND DISMISSAL DECISION

**ABELL**, Special Master:

On 13 November 2007, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),[2] alleging that her husband David suffered fatigue, incontinence, decreased consciousness, balance disturbance, and skin irritation, and

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[1] This opinion constitutes my final "decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Therefore, unless a motion for review of this decision is filed within 30 days after the time given herein to Petitioner to make such filing has elapsed, the Clerk of this Court shall enter judgment in accord with this decision. Moreover, Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

that such was related to the administration of an influenza vaccination on 14 November 2005. Petition (Pet.) at 1. As an alleged vaccine-related injury, Petitioner demanded compensation for unreimbursable expenses for past or future treatment, pain and suffering, and attorney's fees and costs. This Court is jurisdictionally invested with the task of determining whether Petitioner is entitled to compensation. Due to the lack of substantiating proof of the types statutorily-required and amounting to a preponderance of the evidence, the Court denies compensation.

## I. PROCEDURAL HISTORY

Petitioner was represented by able counsel, and filed all of the relevant medical records relating to Petitioner's alleged condition. See Petitioner's Exhibits ("Pet. Ex.") 1-19. After sincere attempts throughout calendar years 2008-09 to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved in a status conference convened on 9 January 2009 for a ruling on the written record, and the Court hereby grants that motion. Respondent filed its Report, pursuant to Rule 4(c), on 29 May 2009, denying compensation, and the Court now rules pursuant to Petitioner's motion.

## II. FACTUAL RECORD

Having been born in 1944, Mr. Reed's medical history is unsurprisingly complex. The development of a bone tumor in the base of his skull required resections and radiation treatments over the course of several years, leaving neurological deficits (including an ataxic gait) and loss of nervous sensation in some areas; however, there remained a calcified mass affecting his brainstem as recently as 1990. Pet. Ex. 16 at 417, 663-64, 702, and 537. Symptomatically, his recent medical history was remarkable for trouble with balance and equilibrium ( Pet. Ex. 16 at 357, 454, 578, and 627) and problems with memory (Pet. Ex. 16 at 289-90).

Petitioner claimed in the Petition that Mr. Reed received an influenza vaccination on 14 November 2005, but no records were filed to support this contention. There are no records even of a doctor's visit on that day.

On 29 November 2005, Mr. Reed reported to the emergency room for a two-week history of weakness that he described as "gradual in onset and ha[d] been waxing and waning," and was noteworthy for loss of balance, feelings of light-headedness, and generalized weakness that grew worse in changed positions. Pet. Ex. 3 at 22. He described being more unstable than he had been previously, having fallen several times, which was reported as a clinical impression of walking difficulty and falling episodes while noting his preexisting ataxia. *Id*. at 23.

Mr. Reed was hospitalized in February 2006 for falling when he lost his balance, and again in March 2006 for severe right groin and hip pain that affected his mobility. Pet. Ex. 4 at 30; Pet. Ex. 6 at 70. The pain that prompted the March hospital visit was attributed to the fall that prompted the February visit. Pet. Ex. 6 at 71.

Mr. Reed showed persistent elevation of liver enzymes, which one doctor thought could have been evidence of a hepatic encephalopathy that might explain the onset of new neurological

symptoms (though his primary care physician and others disagreed with such a diagnosis), one doctor thought might be related to the flu shot reported by Mr. Reed (while another doctor thought it "highly unlikely" that it might be related to influenza vaccination). Pet. Ex. 1 at 9-13; Pet. Ex. 16 at 283, 285-86. Following a liver biopsy in May 2006, the treating physician dismissed any connection between Mr. Reed's liver pathology and his neurological symptoms. Other doctors related the neurological symptoms to Mr. Reed's tumor. Pet. Ex. 16 at 308. Several of Mr. Reed's treating physicians reiterated to him that his symptoms were unrelated to any vaccinations. Pet. Ex. 16 at 280, 296, and 302.

## III. DISCUSSION

This Court is given jurisdiction to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a listed Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). For certain categories of vaccines, the Vaccine Injury Table lists specific injuries and conditions, which, if found to occur within the period prescribed therein, create a rebuttable presumption that the vaccine(s) received caused the injury or condition. §14(a). The vaccine which Petitioner alleges to have caused Mr. Reed's condition(s) was the (trivalent?) influenza vaccine, listed under category XIII on the Vaccine Table. Trivalent influenza is categorized with no coordinate injury assigned. 42 C.F.R. § 100.3(a). Essentially, this relegates all claims upon trivalent influenza vaccine to an "actual causation" theory of relief, under which Petitioner must prove that such vaccine actually caused the injury(ies) alleged.

In this case, the medical records do not support a causative connection between the vaccination Petitioner claims to have been administered and the injuries suffered under an actual causation burden of proof. Under the statute, the Court cannot grant a petitioner compensation based solely on the petitioner's asseverations. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not manifestly support the petitioner's claim, a medical opinion must be offered in support. No medical expert opinion report was filed by Petitioner to support the claims of causation within the Petition to a preponderance of the evidence, and Petitioner therefore did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the Program.

A petition may prevail if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury or condition complained of. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

*Grant*, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

> [A petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury leading to Petitioner's condition, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (2006) (emphasis added), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that the injured party would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

Here, Petitioner has not filed medical records or offered medical expert testimony to proffer, let alone explain, a "medical theory causally connecting the vaccination [to] the injury." Certainly absent was a detailed analysis of the Record to indicate a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." As such, Petitioner has not offered a theory of causation as such, but this is certainly not due to lack of opportunity to present a medical expert opinion. There has not been demonstrated to the Court a "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Q.E.D. See Althen, supra*.

In short, Petitioner has not met the burden of proof set forth in the Act.[3] Petitioner has presented none of the evidence required by the Act in the form of corroborative medical records, and

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[3] *See Raley v. Secretary of HHS*, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) (stating "[t]he requirement that [a] petitioner['s] claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone"); *Bernard v. Secretary of HHS*, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992) ("The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred.").

failed to account for the contrary explanations set forth in the medical records that contradicted their contentions.

## IV. CONCLUSION

Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** this petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, the clerk shall forthwith enter judgment in accordance herewith. **IT IS SO ORDERED.**

s/ Richard B. Abell
**Richard B. Abell**
Special Master